UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/934,482 | 08/23/2001 | Naoya Motegi | ASA-1025 | 8422 |

7590 03/09/2004

MATTINGLY, STANGER & MALUR, P.C.
SUITE 370
1800 DIAGONAL ROAD
ALEXANDRIA, VA 22314

| EXAMINER | |
|---|---|
| SODERQUIST, ARLEN | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1743 | |

DATE MAILED: 03/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/934,482 | MOTEGI ET AL. | |
| | Examiner | Art Unit | |
| | Arlen Soderquist | 1743 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 1-3 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-3 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 5-17-02.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

2. Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over the admitted state of the art or Sakagami (US 4,785,407) in view of Kopf-Sill (US 5,590,052).

The claim format used for the claims is being interpreted as the Jepsen format or the improvement of a known apparatus. In the first part of claim 1 applicant admits an automatic chemical analyzer capable of determining plural components of a sample using independent (different) reagents for the respective components. At least a part or all of the sections for performing fluid transfer, mixing and determination of the reagents, samples and reaction solution under analysis are shared. In order to prevent the occurrence of errors of determination due to contamination, the analyzer is provided with a function to set the determination conditions for judging the presence or absence of contamination and to make an automatic judgment of the combination of items involving contamination. The admitted prior art does not teach how the judgment of contamination is made.

In the patent Sakagami teaches three embodiments of an automatic chemical analyzer including a cuvette wheel (1) having a number of cuvette holding recesses formed along a periphery thereof, a driving unit (1A) for rotating the cuvette wheel in a stepwise manner, an automatic cuvette loader (3) for supplying cuvettes (2) into cuvette holding recesses of the cuvette wheel, a sample delivery device (4) for supplying samples into cuvettes held on the cuvette wheel, a reagent delivery device (5) for supplying a plurality of different reagents into

cuvettes held on the cuvette wheel, at least one colorimeter (6-1,6-2,6-3) for measuring an optical density of test liquids contained in cuvettes, a washing device (7) for washing cuvettes, and an automatic cuvette unloader (8) for removing cuvettes out of the cuvette wheel. The analyzer further comprises a central control device for controlling the automatic cuvette loader and unloader such that after a cuvette has been repeatedly used a predetermined maximum number of times, the relevant cuvette is removed from the cuvette wheel and a new cuvette is supplied into the cuvette holding recess from which the cuvette has been just removed. Figure 2 shows the washing unit in detail. The second and third embodiments are shown in figures 4-7 and include a colorimeter (26) arranged in the washing unit to detect a degree of deterioration, stain or dirtiness (contamination) of one or more. An output signal of the colorimeter is supplied to the control device (24) and is compared with a tolerable threshold level which has been previously stored. When a detected level representing the dirtiness of a cuvette exceeds the threshold level, the relevant cuvette is discharged from the cuvette wheel even though the cuvette has not yet been used the maximum number of times. The invention way have many modifications including using the colorimeter as the sole determiner for when to exchange a cuvette, using a plurality of washing agent liquids that may be selectively supplied to a cuvette in accordance with a test item or using a detected concentration of substance contained in a sample as the condition for exchanging the cuvette when it is measured to be when an abnormally high. Sakagami does not teach using a difference between a pervious measurement and a current measurement as the condition for determining the contaminated condition.

In the patent Kopf-Sill teaches error checking in a blood analyzer. The patent provides various methods for detecting errors in a blood analysis system. The system includes a blood analyzer and cuvettes which contain lyophilized reagents in a rotor. The rotor is placed in the analyzer which spins the rotor, and an optical system reads the cuvettes as light is flashed through the cuvettes. There are checks for various things including things related to contamination: determining dilution systematic failure when measuring different reaction chemistries in the cuvettes of the rotor; determining whether a blood sample in a cuvette is hemolyzed, lipemic, or icteric; and determining the degradation of a reagent in a cuvette. Column 1, lines 58-65 teach it is desirable to provide methods for detecting these and other problems in order to avoid the reporting of false results and improve the accuracy of the fluid

analyzing process. The methods should be able to verify that individual readings and/or groups of readings fall within expected value(s) and range(s) and thus be able to produce an alarm when the readings are improbable and fall outside of the expected value(s) and range(s). the paragraph bridging columns 3-4 teaches a method for determining if diluent in an analytical rotor has been contaminated by bacteria or other materials. The method is performed by distributing only diluent from a diluent source to a cuvette. Light is directed to the cuvette containing only diluent at a wavelength which is differentially absorbed by diluent having differing amounts of contamination and a resulting signal is measured. The signal measured is then compared with an expected value and an error is indicated if the measured signal differs by a predetermined amount from the expected value. A flow chart for this is shown in figure 6. In the comparison step, if the measured value differs from a diluent absorbance limit by a predetermined amount, an error is indicated that the diluent is contaminated and the rotor can be suppressed. In a preferred aspect, the measured signal is compared with the diluent absorbance limit to determine if the measured signal is greater than the limit. If so, the error signal is indicated. Figure 11 illustrates a method used to determine if a blood sample is contaminated by being hemolyzed, lipemic, or icteric. This test is particularly useful for whole-blood analyzers where the user is not given a chance to visualize the serum or plasma and judge its hemolysis, lipemia, or icteric content. The method determines these levels by placing the blood in the rotor and spinning the rotor to deliver the plasma to the cuvettes. A cuvette having a sample blank reagent is then flashed with a series of light flashes having three different wavelengths, preferably, about 340, 405 and 467 nm. A signal is measured for each of the three flashes and then compared in an iterative manner to determine whether the sample is hemolyzed, lipemic, or icteric. The calculations used in this comparison are referred to as sample index calculations. If one of these conditions is satisfied, an error condition is indicated. A further source of error can be in the handling of rotors after they leave the manufacturer's warehouse. Typically, the rotors are packaged in impermeable foil pouches with a desiccant pouch inside and shipped in cold packs to users who store them in cold storage, such as a refrigerator. Before use, the rotors are typically brought to room temperature for at least 20 minutes and generally no longer than 120 hours. Some of the chemistries are adversely affected by exposure to heat, humidity, light, and other environmental conditions resulting in contamination due to reagent degradation. To

determine whether any of the reagents may have been affected by excessive exposure to such conditions, the method illustrated in figure 12 is used to generate an error condition if the rotor has been overexposed to heat, moisture, or to UV or other light. The check is performed by providing at least one test reagent in at least one cuvette which is more sensitive to heat, light, moisture, or other environmental conditions than all other analytical reagents in other cuvettes of the rotor. When the rotor is spun in the analyzer, only diluent is delivered to the cuvette having the test reagent(s). Light is then directed through the test cuvette and a signal is measured. If the signal differs by a predetermined amount from an expected value, the error condition is indicated.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the contamination absorbance limit as taught by Kopf-Sill into the admitted prior art or Sakagami references because of the ability to provide a warning that an analysis result is in error as taught by Kopf-Sill.

3. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited art relates to contamination in automated analyzers.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arlen Soderquist whose current telephone number is (571) 272-1265 as a result of the examiner moving to the new USPTO location. The examiner's schedule is variable between the hours of about 5:30 AM to about 5:00 PM on Monday through Thursday and alternate Fridays.

A general phone number for the organization to which this application is assigned is (571) 272-1700. The fax phone number to file official papers for this application or proceeding is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Arlen Soderquist

March 3, 2004

ARLEN SODERQUIST
PRIMARY EXAMINER